K002353

AUG 1 0 2000

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 576 - 3544

Contact Person: Kay A. Taylor

Date Prepared: July 31, 2000

Device Name

Proprietary name: Elecsys® CA 15-3 CalCheck

Common name: Calibration Verification Material

Classification name: Single (specified) analyte controls (assayed + unassayed)

Predicate device

The Elecsys® CA 15-3 CalCheck is substantially equivalent to the currently marketed Elecsys® Thyroglobulin CalCheck (K001015).

Device Description

The Elecsys® CA 15-3 CalCheck is a lyophilized product manufactured using CA 15-3 in human serum matrix with preservatives. The analyte is appropriately spiked into the CalCheck matrix to the correct concentration levels.

510(k) Summary, Continued

Intended use	The Elecsys® CA 15-3 CalCheck is used in the verification of the calibration established by the Elecsys CA 15-3 reagent on Elecsys 1010 or 2010 immunoassay analyzers.
Comparison to predicate device	The Elecsys® CA 15-3 CalCheck is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys® Thyroglobulin CalCheck (K001015). Both products are intended for use in the verification of calibration established by the respective Elecsys reagent on the Elecsys automated immunoassay analyzers.
Performance Characteristics	The Elecsys® CA 15-3 CalCheck was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 0 2000

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K002353
Trade Name: Elecsys® CA 15-3 CalCheck
Regulatory Class: II
Product Code: JIS
Dated: July 31, 2000
Received: August 2, 2000

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~N/A~~ K002353

Device Name: Elecsys® CA 15-3 CalCheck

Indications For Use:

Elecsys® CA 15-3 CalCheck calibration verification solutions comprise three levels - low, mid, and high - each with a defined CA 15-3 concentration. The low solution concentration is near the lower detection limit of the assay. The mid solution is in the middle or at the clinically critical point of the measuring range. The high solution is near the upper limit of the measuring range.

The Elecsys® CA 15-3 CalCheck is intended for use in periodic verification of the Elecsys® CA 15-3 reagent calibration

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)